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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/039,383

12/17/2001

Hsien-Jue Chu

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03/09/2006

EXAMINER

DEVI, SARVAMANGALA J N

WYETH
PATENT LAW GROUP
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MADISON, NJ 07940

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,383

Applicant(s)

CHU ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/07/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 14-17 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 14-17 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 12/07/05 in response to the non-final Office Action mailed 09/07/05.

Status of Claims

- 2) Claims 10, 11, 14, 15 and 17 have been amendment filed 12/07/05.
Claims 10-12 and 14-17 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 5) The rejection of claim 10 and those dependent therefrom made in paragraph 11 of the Office Action mailed 09/07/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.
- 6) The rejection of claim 10 made in paragraphs 12(a) and 12(b) of the Office Action mailed 09/07/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 7) The rejection of claim 15 made in paragraph 12(c) of the Office Action mailed 09/07/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 8) The rejection of claim 17 made in paragraph 12(d) of the Office Action mailed 09/07/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

9) The rejection of claims 11, 12 and 14-17 made in paragraph 12(e) of the Office Action mailed 09/07/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

10) The rejection of claims 10-12 made in paragraph 13 of the Office Action mailed 09/07/05 under 35 U.S.C § 103(a) as being unpatentable over Petersen *et al.* (WO 92/03157, already of record) and Byars *et al.* (*Vaccine* 5: 223-228, 1987, already of record) in view of Liem *et al.* (US 20020114817, filed 09/29/1999 – already of record), is withdrawn in light of Applicants' amendment to the base claim.

11) The rejection of claim 17 made in paragraph 14 of the Office Action mailed 09/07/05 under 35 U.S.C § 103(a) as being unpatentable over Petersen *et al.* (WO 92/03157) as modified by Byars *et al.* (*Vaccine* 5: 223-228, 1987) and Liem *et al.* (US 20020114817, filed 09/29/1999) as applied to claim 10 above, and further in view of Frantz *et al.* (US 5,695,769) and Pijoan (US 6,585,981), is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Maintained

12) The provisional rejection of claims 10-12 and 14-17 made in paragraph 10 of the Office Action mailed 09/07/05 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-18 of the co-pending application, SN 10/150,597, is maintained for reasons set forth therein and herebelow.

Applicants submit the following arguments: (a) The method claims of the pending application 10/150,597 require the administration of a combination composition that includes at least one viral antigen. (b) The inclusion of the viral antigen provides a patentable distinction in view of the restriction requirement in the continuation-in-part application, wherein the restricted first group comprised the claims drawn to a vaccine composition containing the *Mycoplasma hyopneumoniae* bacterin and a viral antigen, and the second group comprised the claims drawn to a vaccine composition containing the *Mycoplasma hyopneumoniae* bacterin and a bacterial antigen. (c) Based on the reasons set forth in the pending CIP application for separating the two vaccines, it seems reasonable to conclude that the presence of the viral antigen results in a vaccine that is biologically, chemically and structurally different from the vaccine recited in the instant claims 10-12 and 14-17.

Applicants' arguments have been carefully considered, but are not persuasive. The instant claims are not product claims drawn to a vaccine, instead are method claims. There is no restriction requirement in the instant application that separated a method of protecting a porcine animal against *Mycoplasma hyopneumoniae* infection from a method of protecting a porcine animal against *Mycoplasma hyopneumoniae* infection and against a viral antigen. The restriction in the co-pending application between two vaccine species has no bearing in the instant application. Furthermore, it must be noted that the instant claims are method claims that use the genus vaccine composition comprising the *Mycoplasma hyopneumoniae* bacterin. The term 'comprising' in the claim(s) does not exclude a viral antigen being comprised in said vaccine composition. Therefore, although not expressly recited, the instant method claims encompass protecting a porcine animal against viral and/or bacterial infections in addition to protecting against infection or disease caused by *Mycoplasma hyopneumoniae*. For example, see claim 17. Although not expressly recited, the method of claim 17 would be expected to elicit an immune response to at least one of the recited bacterial bacterin in addition to protecting the porcine animal against infection or disease caused by *Mycoplasma hyopneumoniae*. Since the presence of a viral antigen in the recited vaccine composition is not excluded, the method of protecting a porcine animal against disease caused by *Mycoplasma hyopneumoniae* and at least one viral antigen as claimed in the co-pending CIP application falls within the scope of the instant method claims. The provisional rejection stands.

New Rejection(s) Based on Applicants' Amendments

The new rejection set forth below is necessitated by Applicants' amendments to the claims.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

13) Claim 10 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 10, as amended, includes new the limitations: 'wherein said' vaccine composition, after a single administration, elicits protective immunity 'in said porcine animal against said'

Mycoplasma hyopneumoniae infection 'or disease for a duration of six months after the single administration'. However, there is no descriptive support in the specification, as originally filed for the above-identified new limitations or the new scope. The instant specification documents that the protective immunity against *Mycoplasma hyopneumoniae* infection or disease (as measured by lung lesion scores) elicited by the vaccine recited in claim 10 after a single administration for a duration of six months, is limited to porcine animals that were administered said single dose --at the age of three weeks--. See instant specification at lines 3-6 of page 20; lines 3-11 and 14-23 of page 21; lines 1-14 on page 22; lines 19-27 of page 23; Table 5; and the last four lines on page 25. The method of protecting a porcine animal of any age by administering the recited vaccine and eliciting protective immunity against *Mycoplasma hyopneumoniae* infection or disease for a duration of six months following a single administration is not supported in the instant specification. Therefore, the above-identified limitations in claim 10 are considered to be new matter. *In re Rasmussen*, 650 F.2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the originally filed specification where support for the new limitations can be found.

Remarks

14) Claims 10-12 and 14-17 stand rejected.

Claim 17 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP 608.01(n). Accordingly, the claim has not been further treated on the merits.

15) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.

17) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

18) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER